REMARKS

Entry of the above amendments and reconsideration of this application are requested. Upon entry of the amendments, this application will contain claims 43-47, 49, 52-56, 58-60, 62-64, 68 and 73-74. This new set of claims includes two independent claims which were previously pending as dependent claims, and two new independent claims. Particularly, claim 43 has been amended to incorporate the limitations of prior dependent claim 51. Claim 60 has been amended to incorporate the limitations of prior claims 70 and 71, which were sequentially dependent. Claims 44-47, 49, 53-56, 58-59, and 68 are dependent upon claim 43. Some of these have been formally amended in their dependency or preamble to conform to the amendments made to claim 43. Claims 62-64 remain and are dependent upon claim 60. Claims 73 and 74 are new independent claims. Entry of these proposed amendments is requested. Further, it is respectfully submitted that upon entry of the amendments and consideration of the following remarks, this application will be in condition for allowance and such action is requested.

The amendments proposed above simplify the issues remaining in the application. Independent claim 43 is the equivalent of prior dependent claim 51, which stood rejected under 35 USC § 112, first paragraph, and under 35 USC § 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4,888,366 (see page 6 of Office Action). It is submitted that these rejections are inapplicable and thus their withdrawal is solicited.

First, as to the rejection under 35 USC § 112, first paragraph, the Office Action asserts that the term "lyophilized" which was added to the claim in the prior amendment represents new matter, noting that the applicant did not at the time of the amendment point out the support for the amendment. In response, the amendment is supported by the specification at many locations. At page 11, lines 28-30, the application teaches that the implant is freeze dried. In addition, in each of examples 1-4 set forth at pages 14-15, indication is given that the implants are freeze dried. It is submitted that these teachings clearly provide support for the term lyophilized, as one of ordinary skill in the art would understand the correspondence of the two terms. In this regard, it is noted that even the definition for lyophilization provided by the Examiner in the Office Action references freezing and drying. As it is well established in the law that exact correspondence in wording between claims and specification is not required, and because one of ordinary skill in the art would clearly recognize freeze drying as identified in the current specification as lyophilization, it is submitted that the rejection under 35 USC § 112, is inapplicable and should be withdrawn.

With regard to the rejection under 35 USC § 103(a), the Chu et al. patent does not render claim 51 (incorporated now as claim 43) obvious because the Chu et al. reference fails to motivate one of ordinary skill in the art to carry out the claimed invention. Quite the contrary, the Chu et al. reference expressly teach the skilled artisan away from the present claimed invention. Claim 43 is directed to an osteogenic sponge composition that comprises a "three-dimensionally stable but flexible" device. This feature is not taught by the Chu et al. patent and in fact is taught against. Chu et al. expressly state that their preparations are rigid, not spongy. Chu et al. also expressly teach that the manner in which the ingredients in their preparations are processed affects either a rigid or a spongy state to the materials, and expressly teaches against forming things having a spongy state. Particularly as to the rigidity of the Chu et al. implants, it is taught that they are "rigid with a compressive strength of at least 20 Newtons per square centimeter". See column 2, lines 49-51. In teaching this aspect of their invention, Chu et al. expressly state that a controlled drying process at substantially ambient pressure, preferably at slightly elevated temperatures, must be used to obtain the rigid material. Specifically, at column 9, lines 22-26, Chu et al. state:

> This material must be dried at substantially ambient pressure, preferably at slightly elevated temperatures. Drying by lyophilization at the final step produces a spongy product nonconforming with regard to strength and homogeneity.

Numerous references to the necessity of such controlled drying are made in the specification of the Chu et al. patent including at column 9, lines 38-42, column 10, line 4, column 10, lines 64-65, and others. In fact, Example 2 of the Chu et al. patent is set forth as a comparative example, and describes processing by lyophilization. It is important to emphasize in this regard that the Chu et al. reference teaches that lyophilization processing, as opposed to the controlled drying processes, leads to a preparation having different physical properties. Whereas the lyophilization leads to a sponge-form material, drying under their controlled conditions leads to a rigid material. Accordingly, the Examiner's assertion in the Office Action spanning pages 4 and 5, that the materials must be inherently the same because the ingredients are the same, is established as incorrect in the teachings of the reference itself. Moreover, claim 43 as amended requires that the matrix comprise a lyophilized form of collagen. Again, the above-referenced teachings of the Chu et al. reference teach directly against their prepared materials having lyophilized collagen.

In summary, claim 43 as amended requires a sponge device that is three dimensionally stable but flexible, and the Chu et al. patent teaches directly against such a device. Claim 43 as amended includes a device that incorporates a lyophilized form of collagen, and the Chu et al. reference teaches directly against that feature as well. For these reasons at the least, it is submitted that independent claim 43 and its dependent claims are not obvious over the Chu et al. patent, and allowance of these claims is solicited.

As discussed above, claim 60 remains as an independent claim and has been amended to incorporate the features of claims 70 and 71 which depended sequentially therefrom. Claim 71 stands rejected under 35 USC § 102(b) as being anticipated by or, in the alternative, under 35 USC § 103(a) as obvious over the Chu et al. patent discussed above. For the following reasons it is believed that this rejection is inapplicable and should be withdrawn.

First, as discussed above in connection with claim 43, claim 60 requires a device that is "three-dimensionally stable but flexible". The above-made comments with regard to the rigid devices of Chu et al. and its teachings away from flexible sponge devices are fully applicable here. Still further, the claimed implant device is comprised 97-99% by weight of the biphasic calcium phosphate particulate biocompatible mineral. The Chu et al. patent, if anything, teaches one of ordinary skill in the art against this claimed feature as well. Specifically, at column 7, lines 13-38, while Chu et al. teach that the mineral component can include a mixture of hydroxyapatite and tricalcium phosphate, for such compositions Chu et al. state a preference for a mineral content of 95% or less (see in particular lines 25-28 of column 7).

Accordingly, the Chu et al. patent teaches directly against three-dimensionally stable but flexible devices as claimed, and in reference to mixtures of tricalcium phosphate and hydroxyapatite directs the skilled artisan to a lower mineral component than that presently claimed. As such, it is submitted that claim 60 is patentably distinct from the Chu et al. patent, and withdrawal of the subject rejection and allowance of claim 60 and its dependent claims 62-64 is requested.

New claims 73 and 74 have been added to the application. New claim 73 is directed to an osteogenic sponge composition comprising a highly mineralized sponge implant device that is three-dimensionally stable but flexible and consists essentially of a resorbable sponge matrix formed of collagen and having particulate biocompatible mineral embedded within the matrix. The device is comprised 1% to 3% by weight of the collagen and 97% to

99% by weight of the particulate biocompatible mineral, and has been prepared by providing a slurry including the collagen and the particulate biocompatible mineral, freeze-drying the slurry to form a dried sponge material, and crosslinking the dried sponge material to result in a three-dimensionally stable but flexible device. Support for such processing is found, for example, in the preparative Examples of the application. The osteogenic sponge composition also includes an an osteogenic factor. New claim 74 is directed to an osteogenic composition that includes a highly mineralized sponge implant device that is three-dimensionally stable but flexible and comprises a resorbable sponge matrix and a particulate biocompatible mineral embedded within the matrix. The device is comprised 1% to 3% by weight of a material forming said sponge matrix, and 97% to 99% by weight of the particulate biocompatible mineral, wherein said resorbable sponge matrix comprises collagen, and the particulate biocompatible mineral comprises biphasic calcium phosphate. The resorbable sponge matrix has been prepared by a process comprising freeze-drying a slurry including the collagen and particulate biocompatible mineral. The claimed composition also includes an osteogenic factor. It is believed that claims 73 and 74 are allowable, at the least, for reasons similar to those discussed above in conjunction with other claims.

In view of the foregoing amendments and remarks, it is believed that all rejections have been comprehensively addressed and that this application is in condition for allowance containing claims 43-47, 49, 52-56, 58-60, 62-64, 68, and 73-74. Prompt action to that end is respectfully solicited.

Respectfully submitted,

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